

Commonwealth of Kentucky
Division for Air Quality

PERMIT APPLICATION SUMMARY FORM

Completed by: Julian D. Breckenridge

GENERAL INFORMATION:

Name:	Catalent Pharma Solutions, LLC
Address:	1100 Enterprise Drive Winchester, KY 40391
Date application received:	8/21/2007
SIC Code/SIC description:	2834, Pharmaceutical Preparations
Source ID:	21-049-00040
Agency Interest:	813
Activity:	APE20060001 & APE20070001
Permit:	F-05-041 R1

APPLICATION TYPE/PERMIT ACTIVITY:

<input type="checkbox"/> Initial issuance	<input type="checkbox"/> General permit
<input checked="" type="checkbox"/> Permit modification	<input checked="" type="checkbox"/> Conditional major
<input checked="" type="checkbox"/> Administrative	<input type="checkbox"/> Title V
<input checked="" type="checkbox"/> Minor	<input checked="" type="checkbox"/> Synthetic minor
<input type="checkbox"/> Significant	<input type="checkbox"/> Operating
<input type="checkbox"/> Permit renewal	<input type="checkbox"/> Construction/operating

COMPLIANCE SUMMARY:

<input type="checkbox"/> Source is out of compliance	<input type="checkbox"/> Compliance schedule included
<input checked="" type="checkbox"/> Compliance certification signed	

APPLICABLE REQUIREMENTS LIST:

<input type="checkbox"/> NSR	<input checked="" type="checkbox"/> NSPS	<input checked="" type="checkbox"/> SIP
<input type="checkbox"/> PSD	<input type="checkbox"/> NESHAPS	<input type="checkbox"/> Other
<input type="checkbox"/> Netted out of PSD/NSR	<input type="checkbox"/> Not major modification per 401 KAR 51:001, 1(116)(b)	

MISCELLANEOUS:

- ☐ Acid rain source
- ☐ Source subject to 112(r)
- ☐ Source applied for federally enforceable emissions cap
- ☐ Source provided terms for alternative operating scenarios
- ☐ Source subject to a MACT standard
- ☐ Source requested case-by-case 112(g) or (j) determination
- ☐ Application proposes new control technology
- ☒ Certified by responsible official
- ☐ Diagrams or drawings included
- ☐ Confidential business information (CBI) submitted in application
- ☐ Pollution Prevention Measures
- ☐ Area is non-attainment (list pollutants):

EMISSIONS SUMMARY:

Pollutant	Actual (tpy)	Potential (tpy)
PM/PM ₁₀	0.900	11.58
SO ₂	0.040	0.109
NO _x	5.70	15.61
CO	3.14	11.11
VOC	1.22	46.33
<i>Single HAPs</i>		
Methanol	0	< 9
Methyl Ethyl Ketone	0	< 9
<i>Combined HAPs</i>	0	< 22.5

SOURCE DESCRIPTION:

Catalent Pharma Solutions, LLC (formerly Cardinal Health Inc.) produces food, pharmaceutical and chemical products by using various solvents in granulation, coating and drying operations. Primary emission units include pharmaceutical processing units, as well as boilers and storage tanks. The processing units utilize aqueous or solvent solutions to produce the pharmaceuticals. Solvents used in the production of solvent-based pharmaceutical products include Ethanol, Isopropanol, Acetone, Methanol, and Methyl Ethyl Ketone, with a small amount of Acetonitrile used in the QC lab. The volatile organic compounds emitted through solvent processing are controlled by catalytic oxidizers. The Standard Industrial Classification (SIC) Code for this source is 2834, *Pharmaceutical Preparations*.

The potential to emit (as defined in 401 KAR 52:001, Section 1 (56)) of VOC, any single hazardous air pollutant (HAP), and the combination of HAPs are greater than major source thresholds. The uncontrolled potential to emit of PM₁₀ is greater than one hundred (100) tons per year and is allowed by limitations of 401 KAR 59:010. To preclude the applicability of 401 KAR 52:020, *Title V Permits*, and 401 KAR 51:017, *Prevention of Significant Deterioration of Air Quality (PSD)*, the source has requested voluntary federally enforceable permit limits below major source thresholds. Therefore, the source is subject to the provisions of 401 KAR 52:030, *Federally-enforceable permits for non-major sources*.

MINOR REVISION FOR F-05-041 R1

On November 7, 2006, the source submitted an application to the Division for Air Quality for a request to modify the language in the compliance demonstration section for catalytic oxidizers covered under Section 17 of 401 KAR 52:030, Off-Permit and Section 502(b)(10) Changes. A letter dated for February 21, 2007 was sent out to the source, granting the request at the next significant revision for the Compliance Demonstration Method under Section B on page 14 of the permit in paragraph c) to replace the current statement with the following:

- c) The above emission units shall be operated only when the average catalyst bed inlet temperature for the controlling catalytic oxidizer is maintained from 450 °F to 650 °F.*

The Division incorporated this change into permit # F-05-041 R1. Moreover, on August 21, 2007 another application was received for the addition of a New Pan Coater as an insignificant activity along with a name/ownership change. The source formerly known as Cardinal Health PTS, LLC is now called Catalent Pharma Solutions, LLC. The application was deemed complete on March 4, 2008.

EMISSIONS AND OPERATING CAPS DESCRIPTIONS:

Clark County is designated as attainment for all criteria pollutants. To preclude the applicability of 401 KAR 52:020, *Title V permits*, total annual source-wide emissions shall not exceed the following specific limitations on a twelve (12) consecutive month basis:

- (a) Volatile organic compound (VOC) emissions: 90 tons per year;
- (b) Particulate matter (PM/PM₁₀) emissions: 90 tons per year;
- (c) Combined hazardous air pollutant (HAP) emissions: 22.5 tons per year; and
- (d) Single hazardous air pollutant (HAP) emissions: 9 tons per year.

Compliance with these limits shall also make the requirements of 40 CFR Part 63 for major sources of HAP emissions, as incorporated by reference at 401 KAR 63:002, not applicable to this source. Compliance with these limits shall also make the requirements of 401 KAR 51:017, *Prevention of significant deterioration of air quality*, not applicable to this source.

OPERATIONAL FLEXIBILITY:

There were no alternative operating scenarios proposed by the permittee.